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UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/921,533 09/02/97 TORMALA

P 2880/27

HM22/0411

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WASHINGTON DC 20036

EXAMINER

CHANNAVAJJALA, L

ART UNIT

PAPER NUMBER

1615  
DATE MAILED:

04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

6/1/00  
\* Mail was returned to office on 4/24/00  
forwarding time had expired.  
Didn't restart. But sent action to  
new address with note.  
B. Gray

# Office Action Summary

Application No.  
**08/921,533**

Applicant(s)

**Tormala et al**

Examiner  
**Lakshmi Channavajjala**

Group Art Unit  
**1615**



☒ Responsive to communication(s) filed on Jan 31, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-22 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1615

### DETAILED ACTION

Receipt of request for extension of time, request for filing CPA under Rule 1.53(d), supplemental prior art with attachment and preliminary amendment B, all dated 1-31-2000, is acknowledged.

1. The request filed on 1-31-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/921,533 is acceptable and a CPA has been established. An action on the CPA follows.

Examiner maintains the previous rejection of the office action dated 8-31-99, which is as follows:

#### *Claim Rejections - 35 U.S.C. § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6 and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent No. 5084051 to Tormala et al (hereafter '051).

'051 teaches surgical biocomposite material suitable for bone surgical applications comprising a polymeric reinforcing element and bioceramic element, wherein the polymeric reinforcing element could be a mixture of polymers or polymer and porous or non porous bioceramic material (abstract, lines bridging cols. 1 and 2; col. 3, lines 14-53; col. 4, lines 19-68, col 5-6, col. 8, lines 61-68, col. 9-10). The reinforcing polymer is in the form of reinforcing fibers

Art Unit: 1615

resulting composite has good mechanical strength and integrity and is easy to handle. '051 teaches the various methods of manufacturing the composite as claimed in the instant invention and the addition of additives which facilitate bone growth and /or antibiotics in the composite material.

***Claim Rejections - 35 U.S.C. § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5,084,051 to Tormala et al (hereafter '051).

'051 discussed above does not teach the claimed diameter of the reinforcing elements. However, '051 teaches the reinforcing elements to give the required strength to the biocomposite, while at the same time allowing for maximum in growth of bone tissue (col. 7). Therefore, it is the position of the examiner that optimizing the parameters such as diameter or thickness of the fibers of reinforcing polymer as well as the size of the bioceramic particles is well within the scope of ordinary skill in the art, such that the composite allows for the in growth of the bone and fibers impart good mechanical strength to the composite.

Art Unit: 1615

6. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5,084,051 to Tormala et al (hereafter '051) as applied to claims 1-8 and 11-22 above, and further in view of Bonfield et al.

Tormala discussed above does not teach the volume fraction of bioceramic as claimed in the instant invention. Bonfield et al teaches bone composites containing hydroxyapatite and polyethylene composites of 0.3 to 0.5 volume fraction, which imparts fracture toughness to the composite. Accordingly, it would have been obvious for one of a skilled artisan to machine the bone composites having a volume fraction which increases the toughness and strength of the composite and have comparable mechanical properties with that of the bone.

7. Applicant's arguments filed 1-31-00 have been fully considered but they are not persuasive.

Applicants argue that none of the cited references when viewed alone or in combination, neither disclose nor suggest the instant invention, which requires a matrix polymeric component be mixed with a bioceramic component and then a polymeric reinforcing element is combined with the above mixture. However, the primary reference of Tormala et al , US patent 5,084,051 ('051) teaches a combination of bioceramic component and a resorbable element, which includes a reinforcing element, to provide toughness and strength (col. 7, lines 40-55). Further, as required by instant claim 3, '051 teaches reinforcing component in the form of fibers (col. 8, lines 62-67). Finally, '051 teaches that the material component is manufactured from polymers, copolymers or ceramic material and/ or their mixtures or alternatively, the resorbable polymer can be mixed with

Art Unit: 1615

additives such as ceramic powders. (claim 1 and col. 6, lines 22-40). Further, '051 teaches the same materials that constitute resorbable polymers and the ceramic components. Thus, '051 teaches a mixture of resorbable polymer and a ceramic component, as that claimed in the instant invention.

With respect to the teachings of Bonfield et al, applicants urge that the reference merely discloses volume fraction, but does not teach present claims. However, this argument is not persuasive because, Bonfield teaches hydroxyapatite reinforced composite materials and their role in increasing the bone toughness, which is the same field of endeavor as that of Tormala ('051). Accordingly, it is the position of the examiner that it would have been obvious for a skilled artisan at the time of instant invention to prepare bone composites having a suitable volume fraction which increases the toughness and strength of the composite and thus have comparable mechanical properties with that of the bone. This is a case of prima facie obviousness. For the above mentioned reasons, the rejection is deemed to be proper. No claims are allowed.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is (703) 308-2438. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax number for this Group is (703) 305-3592.

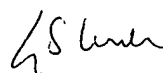
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703-308-1235).



Lakshmi S. Channavajjala



Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1600

04/10/2000